REMARKS

In the Final Office Action dated September 13, 2007, claims 1, 2, 4, 6-8, 10-17, 19, 25-31, 61-62, 64-65, 68-71, 73-77 and 79 were allowed. Claims 54-55, 57-60, 80-84 and 86-89 were rejected. Claims 54 and 80 are amended herein. Amendments have been made without prejudice or disclaimer. No new matter has been added. For at least the reasons set forth herein, applicants submit that the pending claims are patentable and in condition for immediate allowance. Reconsideration is respectfully requested.

Specification

According to instructions in the Final Office Action, the applicants have amended the abstract to comply with the 150 word maximum limit. Reconsideration is respectfully requested.

Claim Amendment

Support for the amendments to claims 54 and 80 may be found at least in FIGS. 1-7 and 11-15 showing a pressurizing element or piston external to the container or vial. Further support may be found in paragraph [0103] describing a device comprising an empty chamber for receiving the medicinal fluid from the vial.

Claim rejections—35 U.S.C. § 103

Claims 54-55, 57-60, 80-84, and 86-89 are rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over U.S. Patent No. 5,330,426 to Kriesel *et al.* in view of U.S. Patent No. 6,607,508 to Knauer.

Kriesel *et al.* disclose a device for intermixing a first component, such as a fluid, with a second component, such as an immobilized drug. Referring to FIG. 7 of Kriesel *et al.*, the device includes hollow housing 12 and a glass vial 30 (the alleged pressurizing element) having a closed end 32 and an open end 34. The open end 34 of the glass vial 30 is closed by a penetrable plug 36 which is telescopically movable within an internal chamber 38 of the glass vial 30.

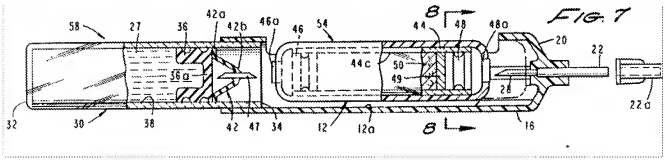

FIG. 7 of Kriesel *et al.*

With continued reference to FIG. 7 of Kriesel *et al.*, it is stated that an "extremely important aspect of the device" is a cartridge 44 (the alleged container) with additive carrying means such as porous substrate or scaffold 50 disposed internally to the cartridge 44 (Kriesel *et al.* column 7, lines 20-27). The additives on the scaffold or substrate 50 are releasably connected and supported in a manner that

the liquid component contained within the glass vial 30 flows about and through scaffold 50, thereby releasing the additives and mixing the additives with the liquid component.

During operation of the device in Kriesel *et al.*, inward pressure on the glass vial 30 causes the penetrable plug 36 to travel longitudinally inside the glass vial 30. The movement of the penetrable plug 36 *within* the glass vial 30 causes the liquid contained within the glass vial 30 to flow through the double ended needle 47 and toward the scaffold or substrate 50 within the cartridge 44.

Amended independent claim 54 recites a medical device cooperable with a needle assembly having a retractable injection needle and a pre-filled container of medicinal fluid. Claim 54 also recites a housing cooperable with the needle assembly and *a pressurizing element external to the container and within the housing* to provide *positive fluid pressure* within the container. Additionally, Claim 54 recites an *empty chamber* in the housing for receiving the medicinal fluid from the container.

Amended independent claim 80 recites a socket for receiving a vial of medicinal fluid, wherein *the socket includes a piston external to the vial to provide positive fluid pressur*e within the vial. Amended claim 80 also recites *an empty* chamber in the housing for receiving the medicinal fluid from the container.

The device in Kriesel *et al.* does obviate a pressurizing element external to the pre-filled container of medicinal fluid as recited by claim 54. Similarly, the device in Kriesel *et al.* does not obviate a socket including a piston external to the vial to provide positive fluid pressure within the vial. As discussed previously, the penetrable plug 36 in Kriesel *et al.* pushes out the liquid from within the glass vial 30.

It would not have been obvious for one of skill in the art to use the specialized Kriesel *et al.* vial 30 with the internal plug 36 to make the recited device which includes a pressurizing element for positively pressurizing a pre-filled standardized medicine vial. The specialized vial of Kriesel *et al.* frustrates the use of the type of vial accommodated by the device recited in the claims of the Present Application.

Furthermore, the device disclosed by Kriesel *et al.* would not have obviated an empty chamber in the housing for receiving the medicinal fluid from the container or vial as recited by amended claims 54 and 80. Kriesel *et al.* disclose a cartridge 44 that is filled with a substrate or scaffold 50 which supports additives that are to be mixed with the liquid supplied by the glass vial 30. In fact, Kriesel *et al.* states that the substrate or scaffold 50 contained within the cartridge 44 is an "extremely important aspect of the device" (Kriesel *et al.* column 7, lines 20-27) implying the necessity of the filled cartridge 44 to the device. None of the embodiments disclosed in Kriesel *et al.* are without the cartridge 44 so that the device as recited in the claims would not meet the purpose and function of Kriesel *et al.* As such, it would not have been obvious to one of skill in the art, in view of the teaching of Kriesel *et al.*, to make or use an empty chamber for receiving the medicinal fluid from the container.

On page 3, the Final Office Action acknowledges that Kriesel *et. al.* do not teach all the elements of the instant claims but alleges that, at the time of the invention, it would have been obvious to add the safety needle assembly of Knauer to the system of Kriesel *et al.* However, even with the safety needle assembly of Knauer, Kriesel *et al.* do not obviate all the limitations of independent claims 54 and 80, and those claims dependent therefrom.

Therefore, Kriesel *et al.* in view of Knauer do not obviate claims 54-55, 57-60, 80-84, and 86-89. As such, applicants respectfully request that the rejection of claims 54-55, 57-60, 80-84, and 86-89 under 35 U.S.C. § 103 (a) be withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicants submit that the pending claims define patentable subject matter and a Notice of Allowance is requested. Should questions exist after consideration of the foregoing, the Office is kindly requested to contact Applicants' attorney at the telephone number given herein.

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